



Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,714	02/13/2001	Seth A. Darst	IPT-011.02	2009

25181 7590 04/26/2004

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Michael Borin

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 23-34 is/are pending in the application.
- 4a) Of the above claim(s) 23-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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DETAILED ACTION

Status of Claims

1. Amendment filed 02/20/2004 is acknowledged. Claims 21,22 are canceled. Claims 23-34 are pending. Claims 1-8, 23-34 are pending.

2. Newly submitted claims 23-34 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The invention as originally claimed is drawn to crystal of RNA polymerase (RNAP). A RNAP molecule, even in its simplest form comprises at least four subunits (see, e.g., Background section, p. 1). The newly submitted claims, however, are drawn not to RNAP, but to "crystallized polypeptides" comprising one or several individual subunits or homologs or derivatives thereof. Thus, the products claimed in the original and newly submitted claims are patentably distinct from each other because of the materially different structures of the compounds they are claiming. Further, a reference teaching a crystal of RNAP will not teach or suggest a "crystallized polypeptide" comprising, e.g., plurality of peptides of SEQ ID No. 1, or even less so, a plurality of peptides that are derivatives of SEQ ID No. 1. Conversely, a reference teaching a "crystallized polypeptide" comprising, e.g., plurality of peptides of SEQ ID No. 1, or even less so, a plurality of peptides that are derivatives of SEQ ID No. 1 will not teach or suggest a crystal of RNAP.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 23-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 introduces new matter as it recites RNAP from eukaryote or prokaryote. There is no disclosure in the specification of crystals of RNAP from any eukaryote, wherein the crystal has resolution as claimed. Applicant refers to page 1 (Background section) , Fig. 5, and p. 61. Neither of them discloses a crystals of RNAP from a eukaryote as now claimed.

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4. Claims 1-3,5-8 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the crystal of *Thermus aquaticus* bacterial core RNA polymerase, which crystal effectively diffracts X-rays for determination of the atomic coordinates to a resolution of better than 3.5A, does not reasonably provide enablement for crystal of any other bacterial or other source core RNA polymerase suitable for same resolution determinations. The rejection is maintained for the reasons of record and in view of the following.

Applicant argues that knowing how to prepare crystals from *Thermus aquaticus* bacterial core RNA polymerase, and given the knowledge in the art on preparation of high quality crystals, one would be able to prepare a crystals of any other RNA polymerase without undue experimentation. Examiner disagrees. In the field of protein crystallography, it is well established that the utilization of a variety of crystallization methods, for the protein in question, greatly improves the chances of identifying suitable conditions for crystallization. However, obtaining suitable single crystal(s) is the least understood step in the X-ray structural analysis of a proteins. Therefore, since the science of protein crystallization is underdeveloped, the crystallization of a protein is mainly a trial-and-error procedure. See, for example a summary of multinational attempt to characterize proteins wherein

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Science Vol. 298, p. 950). Further, it is well known that the homologous proteins from different sources cannot be easily crystallized using the same techniques and/or conditions and may result in different crystal forms. See, for example, Jan Drenth ("Principles of Protein X-ray Crystallography", pages 1-9). While the skill in the art of crystallography is high, the science of protein structure and obtaining protein crystals is uncertain. Even utilizing the same source of protein and conditions for crystallization, a tiny variation in the way of receiving protein structure information and measurements can cause failure in obtaining useful results. Although, working examples are not, *per se*, required, the specification must provide an enabling disclosure for the invention as it is now claimed such that one of ordinary skill in the art could practice the invention without undue experimentation.

5. Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not demonstrate crystal of a core RNA polymerase having omega subunit.

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Applicant points at pages 48, 54 as providing support for the claimed subject matter. However, said portions of the disclosure do not describe crystal of RNAP; rather, they address a possible presence of the subunit in certain RNAP preparations.

Claim Rejections - 35 USC § 102

6. Claims 1-3,5-7 remain rejected under 35 U.S.C. 102(b) as anticipated by Polyakov et al. (Cell, 83, 365-373, 1995). The rejection is maintained for the reasons of record. Applicant argues that the crystal described in the reference diffracted electrons to a much lower resolution, 23 Angstroms. However, while the reference describes the precision of measurements at about 23 Angstrom level (see abstract), such precision might have been limited by researcher's interests or limitations of equipment; at the same time the intended use of the crystal might have been different. In the case of the instantly claimed crystal, 3.5 A is not the actual resolution provided by the crystal, but only an intended use, i.e., an intended use limitation which does not impart patentability to the product as claimed.

Prior art made of record

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7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Todone et al. (PNAS, 97, 12, 6306-6310, 2000) describe crystal structure of universal eukaryotic RNAP subunit (not a crystal of a complete RNAP assembly as claimed) resolved at 1.9 Å.

Conclusion.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0549.

April 21, 2004

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

